

416C-01-F

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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[Docket No. 98F-0797]

Ciba Specialty Chemicals Corp.; Filing of Food Additive
Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp., has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene, as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

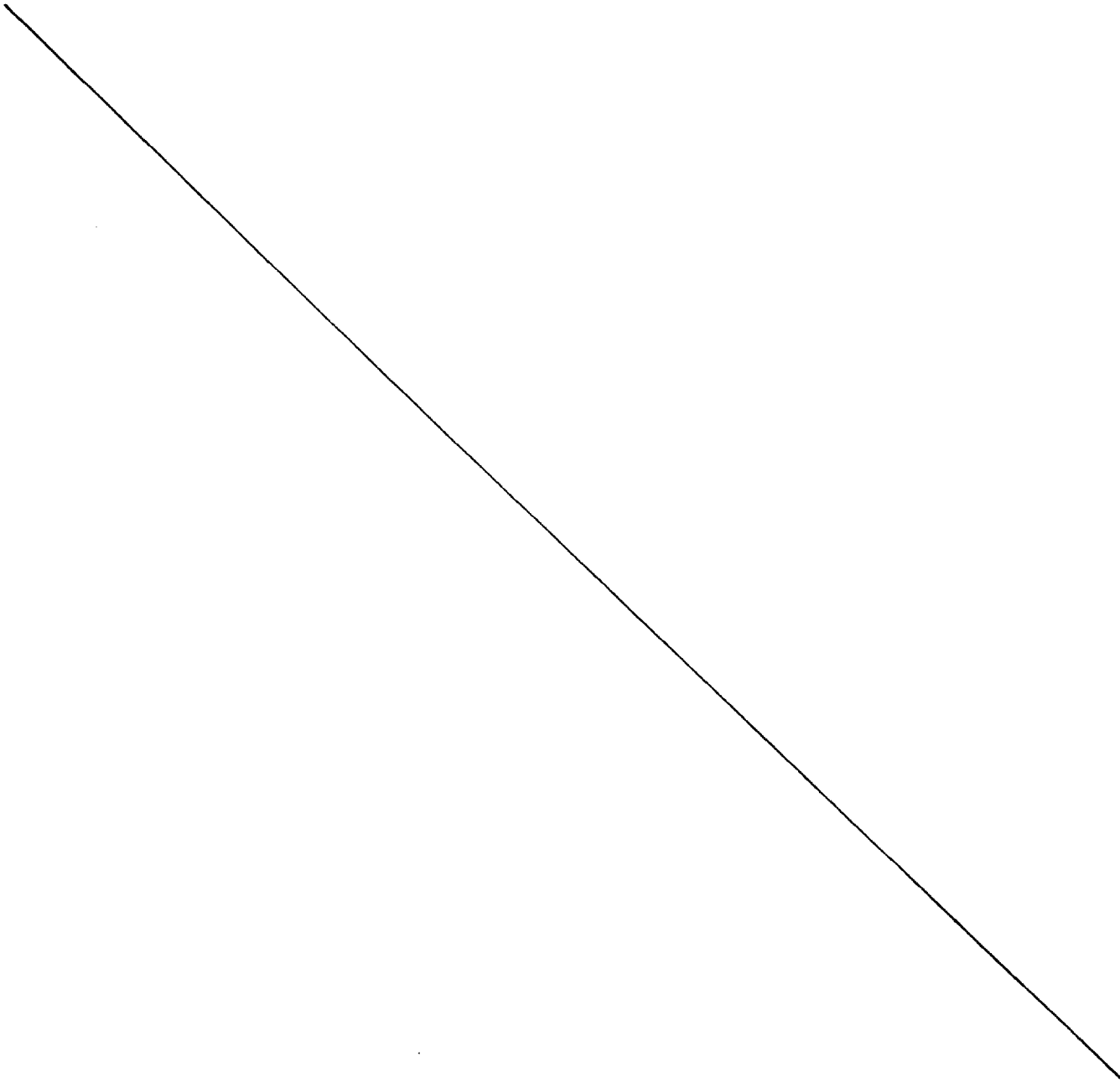
FOR FURTHER INFORMATION CONTACT:

Vir D. Anand,
Center for Food Safety and Applied Nutrition (HFS-215),
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204,
202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4625) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591-9005. The petition proposes to amend the food additive regulations in § 178.2010 Antioxidants and/or

stabilizers for polymers (21 CFR 178.2010) to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as, an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or



cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 4, 1998
September 4, 1998

Signed: Laura M. Tarantino
Laura M. Tarantino
Acting Director, Office of
Premarket Approval, Center for
Food Safety and Applied Nutrition

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

